APR 26 2011

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: February 9, 2011

2. Sponsor
   Wenzhou Wuzhou Import & Export Co., Ltd.
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   Wenzhou, Zhejiang Province, 325000, China
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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4. Proposed Device Identification

   Proposed Device Name: Disposable Insulin Syringe
   Proposed Device Model: 0.3ml, 0.5ml, 1ml
   Classification: II
   Product Code: FMF
   Regulation Number: 21 CFR 880.5860
   Review Panel: General Hospital
   Intended Use Statement:

   Disposable insulin syringe is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

5. Predicate Device Identification

510(k) Number: K072739
Product Name: Sterile Insulin Syringe for single use, with fixed needle
Manufacturer: ShanDong WeiGao Group Medical Polymer Products Co., LTD

6. Device Description

Disposable insulin syringe is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

The proposed device of Disposable Insulin Syringe is a syringe with needle, consisting of a calibrated hollow barrel, a movable plunger, the needle, needle cover and end cap. The needle is fixed on the syringe. The syringe is designed for manual use.

The proposed device of Disposable Insulin Syringe is available in 0.3ml (U-100), 0.5ml (U-40, U-100), 1ml (U-40, U-100) volumes.

The proposed device is provided sterilized.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 8537:2007, Sterile single-use syringes, with or without needle, for insulin.
ISO 9626:1991/Amendment 1:2001, Stainless steel needle tubing for the manufacture of medical devices.
ISO 7864:1993, Sterile hypodermic needles for single use.

8. Substantially Equivalent Conclusion

The proposed device, Disposable Insulin Syringe, is determined to be Substantially Equivalent (SE) to the predicate device, Sterile Insulin Syringe for single use, with fixed needle, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wenzhou Wuzhou Import & Export Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai, China 200237

APR 26 2011

Re: K110421
Trade/Device Name: Disposable Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: February 9, 2011
Received: February 14, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110421

Section II Indications for Use

510(k) Number:
Device Name: Disposable Insulin Syringe

Indications for Use:

Disposable insulin syringe is a device intended for medical purpose for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

PRESCRIPTION USE (Part 21 CFR 801 Subpart D)	[X] OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/26/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110421